

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)RECD 27 MAY 2004  
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Applicant's or agent's file reference JMH/7710-WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/01144	International filing date (day/month/year) 14.03.2003	Priority date (day/month/year) 16.03.2002
International Patent Classification (IPC) or both national classification and IPC G01K13/00, G01K13/00		
Applicant UNIVERSITY OF BRISTOL et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the opinion
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 15.10.2003	Date of completion of this report 26.05.2004
Name and mailing address of the International preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Thomte, M Telephone No. +49 89 2399-2610



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB 03/01144

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-11 as originally filed

**Claims, Numbers**

1-21 received on 15.10.2003 with letter of 15.10.2003

**Drawings, Sheets**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).  
*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-21
	No: Claims	
Inventive step (IS)	Yes: Claims	1-21
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-21
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**ad Section V**

**Re. Clarity matters (Art. 6, PCT)**

1. In claim 4 it is not clear how a printed circuit board is intended to operate as a sensor and it would appear that claim 6 should only refer to claim 5 since no waisted portion has been defined in claims 1 - 4 (to which claim 5 at presently also refers).

**Re. articles 33(2), (3) and (4) PCT**

2. Document EP-A-0 090 327 [= document D1] reveals an ovulation temperature indwelling thermometer comprising a sensor which, by means of a tampon (10), may indwell in the vagina and which thermometer system comprises an electronic temperature sensing means (9) and signal and mechanical indication means (eg the acoustic signal generation - buzzer - means 16) for providing a continuous indication as to whether a predetermined threshold body temperature has been exceeded or not.

The subject-matter of claim 1 differs from what is revealed by document D1 in that the means for providing a continuous indication and the temperature storing means are integral enabling a compact vaginal indwelling thermometer.

It is the provisional opinion of the examiner that even if the ovulation sensor revealed by DE-A-41 22 930 (D2) de facto comprises all necessary technical features integral in a single piece of equipment, this document is nevertheless directed to a temperature measuring device solely to be used in connection with the human ear and does not prompt the the person skilled in the art to use it in other corporal cacvities. Therefore, it woud seem that independent claim 1 and claims 2 - 21 depending thereon, fulfil the requirements of Articles 33(2), (3) and (4) PCT as to novelty, inventive step and to industrial applicability.

3. When pursuing the application in the regional or in the national phase then the following matters should also be dealt with:

- (i) Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 34(2)(b) PCT).
- (ii) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

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EXAMINATION REPORT - SEPARATE SHEET**

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disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

(iii) Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).  
[If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of claim 1 are already known in combination from the document D1 (see the PCT Guidelines, III-2.3a).]

**CLAIMS**

1. A vaginal indwelling thermometer in which the thermometer comprises temperature sensing means, and signal means for providing a continued indication that a predetermined threshold body temperature has been exceeded, integral with means to store temperature data generated by the temperature sensing means and which signal means provides a mechanical indication that the temperature has been exceeded.
2. An indwelling thermometer according to claim 1, in which the signal is selected from the group comprising the movement of an indicator device, the release of a marker dye, vibration of the thermometer, and activation of a buzzer or alarm.
3. An indwelling thermometer according to claim 1 or claim 2, in which temperature sensing means is electronic, chemical or mechanical.
4. An indwelling thermometer according to any one of claims 1 to 3, in which the temperature sensing means comprises a thermochromatic dye, a wax or grease with a specific melting point, a thermodeformable plastics material, a thermocouple linkage, a thermistor or a printed circuit board.
5. An indwelling thermometer according to any preceding claim, in which the thermometer comprises an enclosed hollow container comprising two chambers separated by a waisted portion of the container.
6. An indwelling thermometer according to any preceding claim, in which the waisted portion of the container contains the temperature sensing means.

7. An indwelling thermometer according to claim 6, in which the temperature sensing means is a wax or grease, the melting point of which is at or close to the predetermined threshold temperature.
8. An indwelling thermometer according to any one of claims 1 to 7, in which the signal means is a marker dye contained in one chamber of the container only.
9. An indwelling thermometer according to any preceding claim, in which the data relates to temperatures below and above the predetermined threshold.
10. An indwelling thermometer according to claim 9, in which the predetermined threshold is selected by a computer program.
11. An indwelling thermometer according to claim 10, in which the program is contained within the thermometer.
12. An indwelling thermometer according to any one of claims 1 to 4, in which the thermometer is formed from a plastics material with a thermochromatic pigment or ink incorporated therein.
13. An indwelling thermometer according to claim 12, in which temperature sensing means comprises the thermochromatic pigment or ink and the signal means comprises a fixative to prevent the thermochromatic pigment or ink reverting to its original colour.
14. A kit of thermometers to establish the predetermined threshold temperature of an individual subject mammal, the kit comprising a series of thermometers according to any preceding claim, each thermometer detecting a different predetermined threshold temperature across a range of temperatures.

15. A kit according to claim 14, in which the temperature range is from 35-45°C.
16. Use of an indwelling thermometer according to any one of claims 1 to 13, in which the mammal is a human.
17. Use of an indwelling thermometer according to claim 16, in a human female.
18. Use according to claim 17 for the detection of ovulation.
19. A method of determining ovulation, the method comprising the steps of inserting a thermometer according to any one of claims 1 to 13 into the ear or vagina of a subject mammal, allowing said thermometer to indwell, and periodically observing the signal means to detect a signal.
20. A method according to claim 19, in which the mammal is a human female.
21. A method of determining infection of a mammal, the method comprising the steps of inserting a thermometer according to any one of claims 1 to 10 into the ear or vagina of a subject mammal, allowing said thermometer to indwell, and periodically observing the signal means to detect a signal.

REPLACED BY  
ART 34 AMDT

CLAIMS

1. An indwelling thermometer which indwells in the ear or vaginal cavity of a subject mammal and which the thermometer comprises temperature sensing means and signal means for providing a continued indication that a predetermined threshold body temperature has been exceeded.
2. An indwelling thermometer according to claim 1, in which signal means provides a visual, aural, or mechanical indication that the temperature has been exceeded.
3. An indwelling thermometer according to claim 1 or claim 2, in which the signal is selected from the group comprising the movement of an indicator device, the illumination/quenching of a light, the release of a marker dye, colour change of a thermochromatic ink, vibration of the thermometer, generation of a radio signal, activation of a buzzer or alarm, and a digital telemetry system signal.
4. An indwelling thermometer according to any one of claims 1 to 3, in which temperature sensing means is electronic, chemical or mechanical.
5. An indwelling thermometer according to any one of claims 1 to 4, in which the temperature sensing means comprises a thermochromatic dye, a wax or grease with a specific melting point, a thermodeformable plastics material, a thermocouple linkage, a thermistor or a printed circuit board.
6. An indwelling thermometer according to any one of claims 1 to 5, in which the thermometer is implanted beneath the skin.

7. An indwelling thermometer according to any preceding claim, in which the thermometer comprises an enclosed hollow container comprising two chambers separated by a waisted portion of the container.
8. An indwelling thermometer according to any preceding claim, in which the waisted portion of the container contains the temperature sensing means.
9. An indwelling thermometer according to claim 8, in which the temperature sensing means is a wax or grease, the melting point of which is at or close to the predetermined threshold temperature.
10. An indwelling thermometer according to any one of claims 1 to 7, in which the signal means is a marker dye contained in one chamber of the container only.
11. An indwelling thermometer according to any one of claims 1 to 4, in which the thermometer further comprises means to store temperature data generated by the temperature sensing means.
12. An indwelling thermometer according to claim 11, in which the data relates to temperatures below and above the predetermined threshold.
13. An indwelling thermometer according to claim 11 or claim 12, in which the predetermined threshold is selected by a computer program.
14. An indwelling thermometer according to claim 13, in which the program is contained within the thermometer.
15. An indwelling thermometer according to any one of claims 1 to 6, in which the thermometer is formed from a plastics material with a thermochromatic pigment or ink incorporated therein.

16. An indwelling thermometer according to claim 15, in which temperature sensing means comprises the thermochromatic pigment or ink and the signal means comprises a fixative to prevent the thermochromatic pigment or ink reverting to its original colour.
17. A kit of thermometers to establish the predetermined threshold temperature of an individual subject mammal, the kit comprising a series of thermometers according to any preceding claim, each thermometer detecting a different predetermined threshold temperature across a range of temperatures.
18. A kit according to claim 17, in which the temperature range is from 35-45°C.
19. Use of an indwelling thermometer according to any one of claims 1 to 16, in which the mammal is a human.
20. Use of an indwelling thermometer according to claim 19, in a human female.
21. Use according to claim 20 for the detection of ovulation.
22. A method of determining ovulation, the method comprising the steps of inserting a thermometer according to any one of claims 1 to 16 into the ear or vagina of a subject mammal, allowing said thermometer to indwell, and periodically observing the signal means to detect a signal.
23. A method according to claim 22, in which the mammal is a human female.

24. A method of determining infection of a mammal, the method comprising the steps of inserting a thermometer according to any one of claims 1 to 16 into the ear or vagina of a subject mammal, allowing said thermometer to indwell, and periodically observing the signal means to detect a signal.